

Instrument for Pre-Accession assistance (IPA) newsletter to EU candidate countries

February 2026

Dear all,

Welcome to the fourth edition of EMA's newsletter for EU candidate and potential candidate countries under the Instrument for Pre-Accession Assistance (IPA) programme.

In this quarterly update, we aim to provide a structured overview of upcoming training opportunities, highlight newly added courses in the EU Network Training Centre, and share relevant news and updates from across your networks.

We hope you find these regular updates useful. If you have suggestions, ideas, or contributions for future editions, please feel free to share them with us — your input is always welcome.

I Candidate country in focus – Bosnia and Herzegovina



The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina (ALMBIH) is the national competent authority responsible for medicinal products and medical devices for human use. Established in 2008 in accordance with the Law on Medicinal Products and Medical Devices, the Agency operates under the supervision of the Ministry of Civil Affairs of Bosnia and Herzegovina.

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina (ALMBIH) continues to advance its role as the national authority responsible for regulating

the safety, quality, and availability of medicinal products and medical devices. Its mandate covers the authorization of medicines and medical devices, oversight of clinical trials, supervision of manufacturers and wholesalers, price regulation, quality control, pharmacovigilance, and the monitoring of medicinal product utilization. ALMBIH also conducts regulatory inspections, governs advertising and information practices in the pharmaceutical sector, and publishes the annual Register of authorized medicines.

Since its establishment, ALMBIH has prioritized building strong international partnerships, with a clear commitment to aligning its regulatory framework with European standards. Over the years, the Agency has implemented EU Twinning projects with Spain's AEMPS, fully engaged with the European Directorate for the Quality of Medicines & HealthCare (EDQM), and actively participated in EU Instrument for Pre-Accession Assistance programs. ALMBIH has also benefited from support through WHO regulatory initiatives and, since 2019, holds full membership in the WHO Program for International Drug Monitoring administered by the Uppsala Monitoring Centre. Additionally, the Agency maintains close bilateral and multilateral cooperation with regulatory authorities in Southeast Europe.

In 2025, ALMBIH proposed an extensive package of updated secondary legislation designed to harmonize national regulations with EU law. This includes revised rulebooks governing marketing authorization, pharmacovigilance, quality control, clinical trials for both medicinal products and medical devices, and labelling of medicinal product

packaging. While most of these regulatory updates are expected to be adopted in 2026, the rulebook on the classification of medicinal products has already entered into force following its adoption in 2025.

As of 1 February 2026, Bosnia and Herzegovina will become the first country in the region to implement eCTD for medicinal product marketing authorization procedures.

II Updates from candidate countries

Please see below updates from EU candidate countries:

- From 9 to 12 December 2025, a **TAIEX Expert Mission took place in Tirana at the Albanian National Agency for Medicines and Medical Devices (AKBPM)**, focusing on the assessment of the Agency's institutional and administrative resources. The mission involved the Marketing Authorisation, Pharmacovigilance and Inspection Departments, with experts identifying functional gaps and areas requiring further strengthening. Drawing on EU best practices, the experts proposed legal and administrative measures to support the development of an efficient, sustainable and EU-aligned regulatory authority.
- In 2025, **the Republic of Moldova adopted Law No. 153/2025 on medicinal products, which revises the regulatory framework for medicinal products and aligns it with the provisions of Directive 2001/83/EC** on the Community code relating to medicinal products for human use, as part of the broader alignment with the EU acquis. The law is being implemented through the development and adoption of secondary legislation required for its effective application.
- **Montenegro** is currently actively participating in the preparation of **Joint Actions together with other Member States under the EU4Health Programme**, specifically in the areas of GMDP inspections and clinical trials.
- Discussions are ongoing regarding the **possible involvement of Montenegrin assessors in the INcreaseNET project**, with the aim of further strengthening regulatory and assessment capacities.
- **Montenegro's new Law on Medicines is scheduled for adoption by the Parliament in the beginning of February**. Its expected swift adoption will be followed by the alignment and adoption of implementing bylaws in the fields of human and veterinary medicines.
- **Montenegro has published the newly translated ICH GCP (R3) guidelines** on the CInMED website. In addition, procedures related to GCP inspections have been revised. See more [here](#).
- CInMED's **implementation of electronic submission of documentation** is currently underway, along with the issuing of electronically signed decisions.
- The **laboratory of CInMED continues to expand its capacities**. A new 3D printer has recently been delivered, contributing to the further development of scientific and research activities within the Institute.

III News from EMA

- In 2025, [EMA recommended 104 medicines for marketing authorisation](#). Of these, 38 had a new active substance which had never been authorised in the European Union (EU) before and 16 were granted for medicines for rare diseases.
- On the veterinary side, in 2025, [EMA recommended 30 veterinary medicines for marketing authorisation](#) - the highest number of recommendations ever in a year for a second consecutive year.
- See here also EMA Executive Director Emer Cooke's [end-of-year message on achievements in medicine regulation](#).
- EMA and the U.S. Food and Drug Administration (FDA) have jointly identified [ten principles for good artificial intelligence \(AI\) practice in the medicines lifecycle](#).
- In December 2025, the European Commission, the European Parliament and the Council of the European Union reached an [agreement on the new EU pharmaceutical legislation](#).
- The second [European Sales and Use of Antimicrobials for Veterinary Medicine \(ESUAvet\) annual surveillance report](#) was published in December 2025 indicating small increase in sales. Alongside this report, a new interactive dashboard was launched offering data on VMP sales.

Find more news, see the [EMA website](#).

IV Training opportunities

Please see below the upcoming training opportunities (and also attached the updated training schedule for 2026):

- **Webinar for stakeholder engagement on the new draft guideline on general considerations for patient preference studies (ICH E22)** will take place on Friday, 6 February. For more information and the live broadcast, click [here](#).
- **RAGNA deep dive on bacteriophages** where the history, potential for difficult-to-treat infections (especially in the context of AMR), and the capacity to deliver across One Health will take place on 16 February. Invitation will be circulated closer to the date.
- On 2 March EMA is organising a **Webinar on the use of platform technologies in the non-clinical and clinical domains**. For more information and link to the broadcast, click [here](#).
- **EU4H11-EMA Joint Training initiative: Basic training on radiopharmaceuticals** will take place on 3rd of March online. Link to the training will be provided closer to the training and circulated via e-mail.
- **EMA Veterinary Medicines Info Day 2026** will take place on 12-13 March. Event will be broadcast live. We are also looking into possibilities to offer in-person attendance for candidate countries. More info [here](#).
- We are forwarding you an invitation from the Romanian Medicines Serialisation Organisation (OSMR) and the National Agency for Medicines and Medical Devices from Romania (ANMDMR) to a **conference "Patient Safety through Safe Medicine"** on 24 March. See more in the attached pdf invitation.

V EU NTC international catalogue

- [Pharmacoepidemiology and Real-World Evidence \(RWE\) training curriculum](#) which aims at training regulators and scientists for the collection, analysis, interpretation and use of observational/real-world data for regulatory evaluation and decision-making on medicinal products
- The recording of the webinar on [Effectiveness of risk minimisation measures \(RMMs\) - case studies and practical experience with quantitative and qualitative impact research conducted under the remit of the PRAC Impact Strategy](#) aimed at developing and improving assessment skills needed to optimally fulfil the pharmacovigilance assessor's role with regards to the evaluation of RMM effectiveness.
- [Updated EU NTC LMS Guide](#) to assist navigating the updated user interface of EU NTC.
- [EMA - PIC/S Seminar on Annex 1 to the GMP guideline \(Manufacture of Sterile Medicinal Products\)](#) intended to help GMP inspectors assess sterile facilities in accordance with the requirements of the revised Annex 1.

Find here the [EU NTC platform](#). For new users, please register [here](#).

With kind regards,
Katre & Michiel